UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

November 9, 2022
Date of Report (Date of earliest event reported)

Aprea Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-39069**	**84-2246769**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

535 Boylston Street **Boston, Massachusetts**	**02116**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(617) 463-9385**

(Former name or former address, if changed since last report): Not applicable

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Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common stock, par value $0.001 per share	APRE	NASDAQ Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Item 2.02 Results of Operations and Financial Condition

On November 9, 2022, the Company issued a press release announcing its financial results for the third quarter ended September 30, 2022 and an update on the Company's operations for the same period. The Company is furnishing a copy of the press release, which is attached hereto as Exhibit 99.1.

In accordance with General Instruction B.2 of Form 8-K, the information included in this Item 2.02, including Exhibit 99.1 hereto, shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any filing made by the Company under the Exchange Act or Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press release issued by Aprea Therapeutics, Inc. dated November 9, 2022.
104	Cover Page Interactive Data File (embedded within the inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Aprea Therapeutics, Inc.

Dated: November 9, 2022

By: /s/ Oren Gilad
Name: Oren Gilad
Title: President and Chief Executive Officer

Exhibit 99.1

Aprea Therapeutics Reports Third Quarter 2022 Financial Results and Provides Update on Business Operations

BOSTON, MA, November 9, 2022 (GLOBE NEWSWIRE) -- Aprea Therapeutics, Inc. (Nasdaq: APRE), a biopharmaceutical company focused on developing and commercializing novel synthetic lethality-based cancer therapeutics targeting DNA damage response (DDR) pathways today reported financial results for the three and nine months ended September 30, 2022 and provided a business update.

“We are excited about the advancement of ATRN-119, the first macrocyclic ATR inhibitor, into clinical development,” said Oren Gilad, Ph.D., President and Chief Executive Officer of Aprea. “We look forward to collecting clinical data from our Phase 1 trial.”

Third Quarter Financial Results

- **Cash and cash equivalents:** As of September 30, 2022, the Company had $33.1 million of cash and cash equivalents compared to $53.1 million of cash and cash equivalents as of December 31, 2021. The Company believes its cash and cash equivalents as of September 30, 2022 will be sufficient to meet its current projected operating requirements through the end of 2023.

- **Research and Development (R&D) expenses:** R&D expenses were $1.1 million for the quarter ended September 30, 2022, compared to $6.0 million for the comparable period in 2021. R&D expenses for the quarter ended September 30, 2022 primarily represented close out costs for (i) the Company’s pivotal Phase 3 clinical trial of eprenetapopt with azacitidine for the frontline treatment of *TP53* mutant MDS, (ii) the Company’s Phase 2 post-transplant MDS/AML clinical trial, (iii) the Company’s Phase 1 AML trial, and (iv) the Company’s Phase 1/2 solid tumor trial and the Company’s Phase 1 dose-escalation trial of APR-548 as well as decreased non-cash stock-based compensation expense resulting from the acceleration of vesting of all outstanding stock options and restricted stock units in connection with the acquisition of Atrin in May 2022.

- **General and Administrative (G&A) expenses:** G&A expenses were $3.1 million for the quarter ended September 30, 2022, compared to $3.4 million for the comparable period in 2021. The decrease in G&A expenses was primarily due to decreased non-cash stock-based compensation expense resulting from the acceleration of vesting of all outstanding stock options and restricted stock units in connection with the acquisition of Atrin in May 2022, offset in part by increased professional fees.

- **Net loss:** Net loss was $4.0 million, or $0.12 per share for the quarter ended September 30, 2022, compared to a net loss of $9.5 million, or $0.45 per share for the quarter ended September 30, 2021. The Company had 52,237,885 shares of common stock outstanding as of September 30, 2022. The increased common stock outstanding resulted primarily from the conversion of 2,821,033 shares of Series A preferred stock into 28,210,330 shares of common stock during the third quarter of 2022.

Business Operations Update:

DDR Programs

ATRN-119 – ATRN-119 is an orally-bioavailable, highly potent and selective macrocyclic small molecule inhibitor of ATR, a protein with key roles in response to DNA damage. The Company is conducting a Phase 1 clinical trial to evaluate ATRN-119 monotherapy in cancer patients with defined genetic mutations. This trial was activated and opened for enrollment in the third quarter of 2022 and the Company expects to open 1-2 additional sites in the fourth quarter of 2022.

ATRN-W1051 – ATRN-W1051 is an orally-bioavailable, highly potent and selective small molecule inhibitor of WEE1, a key regulator of multiple phases of the cell cycle. ATRN-W1051 is currently in preclinical development and the Company anticipates commencing IND-enabling studies in the fourth quarter of 2022.

p53 Reactivator Programs

Eprenetapopt - APR-246, or eprenetapopt, is a small molecule p53 reactivator that has been tested in clinical trials for solid tumors and for hematologic malignancies. We currently have no ongoing clinical trials of eprenetapopt.

APR-548 - APR-548 is a second generation p53 reactivator that is being developed in an oral dosage form. We initiated a Phase 1 clinical trial testing APR-548 in relapsed/refractory MDS and AML and enrollment in the first dosing cohort was completed. There are currently no patients receiving APR-548 in this trial and enrollment into the trial has been closed.

About Aprea Therapeutics, Inc.

Aprea Therapeutics, Inc. is a biopharmaceutical company headquartered in Boston, Massachusetts with research facilities in Doylestown, Pennsylvania, focused on developing and commercializing novel cancer therapeutics that target DNA damage response pathways. The Company's lead program is ATRN-119, an orally-bioavailable, highly potent and selective macrocyclic small molecule inhibitor of ATR, that is being tested in a Phase 1 clinical trial in solid tumor indications. ATRN-W1051, the Company's novel WEE1 inhibitor, is in preclinical development. For more information, please visit the company website at www.aprea.com.

The Company may use, and intends to use, its investor relations website at https://ir.aprea.com/ as a means of disclosing material nonpublic information and for complying with its disclosure obligations under Regulation FD.

Forward Looking Statement

Certain information contained in this press release includes "forward-looking statements", within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, related to our study analyses, clinical trials, regulatory submissions, and projected cash position. We may, in some cases use terms such as "future," "predicts," "believes," "potential," "continue," "anticipates," "estimates," "expects," "plans," "intends," "targeting," "confidence," "may," "could," "might," "likely," "will," "should" or other words that convey uncertainty of the future events or outcomes to identify these forward-looking statements. Our forward-looking statements are based on current beliefs and expectations of our management team that involve risks, potential changes in circumstances, assumptions, and uncertainties. Any or all of the forward-looking statements may turn out to be wrong or be affected by inaccurate assumptions we might make or by known or unknown risks and uncertainties. These forward-looking statements are subject to risks and uncertainties including risks related to the success and timing of our clinical trials or other studies, risks associated with the coronavirus pandemic and the other risks set forth in our filings with the U.S. Securities and Exchange Commission. For all these reasons, actual results and developments could be materially different from those expressed in or implied by our forward-looking statements. You are cautioned not to place undue reliance on these forward-looking statements, which are made only as of the date of this press release. We undertake no obligation to publicly update such forward-looking statements to reflect subsequent events or circumstances.

Source: Aprea Therapeutics, Inc.

Corporate Contacts:

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Sr. Vice President and Chief Financial Officer
617-463-9385

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Sr. Vice President and Chief Operating Officer
617-463-9385

Aprea Therapeutics, Inc.
Condensed Consolidated Balance Sheets
(Unaudited)

	September 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 33,112,601	$ 53,076,052
Prepaid expenses and other current assets	361,178	3,508,358
Total current assets	33,473,779	56,584,410
Property and equipment, net	12,237	23,870
Right of use lease and other noncurrent assets	135,888	215,183
Total assets	$ 33,621,904	$ 56,823,463
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,136,064	$ 1,773,032
Accrued expenses	2,751,524	5,352,996
Lease liability—current	110,551	190,471
Total current liabilities	3,998,139	7,316,499
Lease liability—noncurrent	--	--
Total liabilities	3,998,139	7,316,499
Commitments and contingencies		
Preferred stock, par value $0.001; 128,597 and 0 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	2,998,537	--
Stockholders' equity:		
Common stock, par value $0.001; 52,237,885 and 21,859,413 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively.	52,237	21,859
Additional paid-in capital	328,167,899	240,978,439
Accumulated other comprehensive loss	(10,240,645)	(10,358,956)
Accumulated deficit	(291,354,263)	(181,134,378)
Total stockholders' equity	26,625,228	49,506,964
Total liabilities and stockholders' equity	$ 33,621,904	$ 56,823,463

Aprea Therapeutics, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 1,117,576	$ 6,015,616	$ 15,870,867	$ 19,433,721
General and administrative	3,082,618	3,414,795	18,849,549	10,183,953
Acquired in-process research and development	--	--	76,020,184	--
Total operating expenses	4,200,194	9,430,411	110,740,600	29,617,674
Other income (expense):				
Interest income (expense)	151,123	(33)	205,585	(1,678)
Foreign currency (loss) gain	24,353	(21,907)	315,130	247,233
Total other income (expense)	175,476	(21,940)	520,715	245,555
Net loss	$ (4,024,718)	$ (9,452,351)	$ (110,219,885)	$ (29,372,119)
Other comprehensive income (loss):				
Foreign currency translation	26,161	(207,608)	118,311	(417,438)
Total comprehensive loss	(3,998,557)	(9,659,959)	(110,101,574)	(29,789,557)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.12)	$ (0.45)	$ (4.17)	$ (1.39)
Weighted-average common shares outstanding, basic and diluted	34,655,750	21,231,584	26,453,091	21,201,910